

WEEK ENDING JUNE 12, 2015

OPP Weekly Activity Report

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BIOLOGICAL & ECONOMIC ANALYSIS DIVISION

ISO-17025 Accreditation by A2LA Accrediting Body. The Review Board of our Accrediting Body has now approved all corrective actions submitted for the audit conducted on ACB in December 2014. The ACB is now approved for continued accreditation to the ISO-17025 2005 Standard through March 31, 2017, based on any surveillance audit activities that may occur between now and then. (Paul Golden, 410-305-2960)

Regulatory Aspects of Antimicrobials Presented at OSAP. Steve Tomasino participated in the 2015 Annual Symposium of the Organization for Safety, Asepsis and Prevention (OSAP). The symposium was held in Baltimore on May 28-31. OSAP is a non-profit organization dedicated to the education, research, and policy development for safe and effective control of infectious diseases in the dental healthcare setting. Attendees included oral healthcare workers, dental educators, clinicians, researchers, consultants and industry representatives. Tomasino was a member of a federal panel which included officials from the CDC, FDA, and OSHA and provided the EPA's perspective on biofilm methodologies and the potential for product label claims. (Stephen Tomasino, 410-305-2976)

Kickoff Meeting Set for the New OECD Workgroup. Steve Tomasino has been working with OECD officials to coordinate the launch of the newly formed OECD Expert Group on Efficacy of Microbicides on Hard Surfaces. The international group will be led by EPA and is designed to facilitate harmonization efforts associated with test methods for antimicrobial products. The harmonized use of the OECD Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides used on Hard Non-Porous Surfaces is the priority. The Guidance Document was developed under the auspices of the OECD's Task Force on Biocides and approved by the Working Group of National Coordinators of the Test Guidelines Program in 2013. Since 2013, the EPA has been actively working to further improve the OECD method and to assess its performance across laboratories. The EPA plans to initiate an implementation strategy for the use of the OECD method for antimicrobial product registration in the U.S. The kickoff meeting is scheduled for July 2. A scope of work for new group was previously prepared and reviewed by OECD officials. (Stephen Tomasino, 410-305-2976)

REGISTRATION DIVISION

Registration Division Posts 30-Day Public Comment Period on Isofetamid. On June 5, the Fungicide Branch posted a proposed decision document on the fungicide, isofetamid, for a 30-day public comment period which closes on July 6, 2015. Isofetamid is being proposed for foliar use on almonds; the small vine climbing fruit subgroup 13-07F, except fuzzy kiwifruit; lettuce (head and leaf); the low growing berry subgroup 13-07G; the rapeseed subgroup 20A; and turf grass for golf courses (greens, tees, fairways), sod farms, college and professional sports fields; and residential and commercial lawns. Three proposed products to be conditionally registered are: Technical Isofetamid Fungicide (technical formulation) and Isofetamid 400 SC Fungicide and Isofetamid Turf Fungicide (two end-use formulations). Isofetamid is a broad-spectrum fungicide with preventative, systemic, and curative properties for foliar and soil-borne diseases. As proposed, it would be applied in scheduled protective programs and used in a spray rotation program with products that have a different mode of action. Isofetamid is a phenyl-oxo-ethyl thiophene amide and is a succinate dehydrogenase inhibitor (SDHI), which causes adverse effects on plant and fungi respiration. In consideration of the toxicological information on isofetamid compared to several registered alternatives, isofetamid presents a favorable human health and ecological hazard profile. (Heather Garvie, 703/308-0034)

Registration Actions Completed Under the Pesticide Registration Improvement Act (PRIA)					
Chemical	Company	Registration Number	Action Code*	Due Date	Response Date
The Fungicide Branch granted:					
Myclobutanil	Nufarm Americas, Inc.	228-731	R310	7/10/2015	6/10/2015
Metconazole	Kureha Corporation	72078-1	R170	7/6/2015	6/11/2015
			R175		
Maryam Muhammad, 703/347-030					
Chlorothalonil	Sipcam Agro USA, Inc.	60063-55	R310	6/18/2015	6/8/2015
Craig Reeves, 703/347-0486					
The Fungicide & Herbicide Branch granted:					
Glufosinate	Chemstarr LLC	81964-6	R333	8/3/2015	6/11/2015
Banza Djapao, 703/305-7269					
The Herbicide Branch granted:					
Bromoxynil	NuFarm Limited	35935-2	R351	8/3/2015	6/5/2015
octanoate					
Juanita Gilchrist,703/ 305-6965					
The Invertebrate & Vertebrate Branch 1 granted:					
Piperonyl butoxide	Pyranha, Inc.	21165-34	R340	7/13/2015	6/11/2015
Jennifer Gaines, 703/305-5967					
PRIA Code Category					
R170 – Additional food use ⁽³⁾ (4); R175 – Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups ⁽³⁾ (4): R310 – New end-use or					

R170 – Additional food use⁽³⁾ (4); R175 – Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups⁽³⁾ (4); R310 – New end-use or manufacturing-use product with registered source(s) of active ingredient(s); includes products containing two or more registered active ingredients previously combined in other registered products; requires review of data package within RD only; includes data and/or waivers of data for only: product chemistry and/or acute toxicity and/or public health pest efficacy and/or child resistant packaging⁽²⁾ (3); R333 – New product; MUP or End use product with unregistered source of active ingredient; requires science data review; new physical form; etc. Cite-all or selective data citation where applicant owns all required data⁽²⁾ (3); R340 – Amendment requiring data review within RD (e.g., changes to precautionary label statements)⁽²⁾ (3); and R351 – Amendment adding a new unregistered source of the active ingredient⁽²⁾ (3).

BIOPESTICIDES & POLLUTION PREVENTION DIVISION

BPPD Participates in Biotechnology Risk Assessment Grants Meeting. On June 4, a conference was held at USDA Riverdale to bring together scientists who have received grants to address biotechnology risk assessment issues. Presentations from USDA's Animal and Plant Health Inspection Service, FDA's Center for Food Safety and Applied Nutrition, and OPP were made, followed by posters sessions and discussions with the grant recipients. Several posters on modelling systems for insect resistance management, movement of Cry protein resistant insect populations, and aquatic hazard analysis for corn stubble were presented. (John Kough, 703-308-8267)

OPP Tours the BEAD Lab at EPA's Environmental Science Center. On June 4, BPPD and EFED toured EPA's Environmental Science Center located at Fort Meade, MD. The laboratory is the sole repository for pesticide standards provided to state and federal laboratories in support of FIFRA enforcement. The Analytical Chemistry Laboratory specializes in new formulations and validation methods for collaborative state and federal statutes. The Microbiology Laboratory provides technical and diagnostic support services to OPP for pesticide registration and enforcement programs by researching and developing new testing standards. The tour included a presentation on the Biosafety level 2 and 3 laboratories and demonstrations on antimicrobial testing. (Jennifer Wingeart, 703-347-0100)

ENVIRONMENTAL FATE & EFFECTS DIVISION

OAPTF Modeling Approaches for Arsenic Chemistry in Soil. On June 9, OPP met with members of the Organic Arsenical Products Task Force (OAPTF) to discuss their proposed modeling approaches for addressing arsenic chemistry in soils. OAPTF is a registrant group formed in response to a data call-in request for pesticide products containing the salts of monomethyl arsenic acid (MAA). During the meeting, the OAPTF proposed model refinements to include arsenic speciation modeling in soil solution, partial-equilibrium modeling for consideration of reaction rates, and modeling of arsenic sorption in soils. The task force proposed to focus the model development on addressing speciation, adsorption in soils and microbial transformations of MSMA (monosodium salt of methanearsonic acid) as a function of soil pH, soil redox potential, and soil mineral composition. These soil properties would be derived either directly or indirectly from USDA's SURRGO (Soil Survey Geographic) database. There was considerable discussion of the utility and practicality of the proposed model refinements for predicting MSMA and inorganic arsenic concentrations in surface and ground water. Additional discussions with the OAPTF are planned for the near future (Jim Hetrick, 703-305-5237).

<u>Meeting</u>. On June 9, Chuck Peck (EFED) attended this year's meeting of the California Pesticide Use Reporting (PUR) Workgroup and co-authored a presentation with the National Marine Fisheries Service on the use of the data in the upcoming endangered species pilot Biological Evaluations (BEs) and Biological Opinions (BiOps) for chlorpyrifos, diazinon, and malathion. EFED is planning on using the data qualitatively to inform the weight of evidence analysis for the pilot chemical BEs. Other presentations at the meeting examined the development of a new internet-based GIS tool to access the PUR data and to use

the data for guiding risk assessments in national parks and for informing surface water sampling programs (Chuck Peck, 703-347-8064).

EPA Attends Council for the Conservation of Migratory Birds Staff Meeting. On June 8, staff from the EPA attended a Council for the Conservation of Migratory Birds (CCMB) staff meeting at the Department of Interior offices in Washington, DC. The CCMB is an inter-agency council that has representatives from over 20 federal agencies, including the EPA. The meeting included a debrief from the annual CCMB meeting that was held in May. Updates were also provided on several staff committee initiatives, including coordination efforts with the Interagency Sustainability Working Group, the General Services Administration, the National Park Service's Natural Sounds Night Skies Division, and the North American Bird Conservation Committee. There was also a discussion of the past and future Council themes (i.e., facilities management and environmental review, respectively). The meeting ended with updates from several Council staff subcommittees (i.e., Conservation Measures Subcommittee, Award Subcommittee, the Avian Resources Subcommittee, and the Annual Report Subcommittee) (Melissa Panger, 703-305-6136; Cathy Eiden, 703-305-7887).

PESTICIDE RE-EVALUATION DIVISION

<u>OPP Publishes Batch Product Cancellation Order</u>. On June 3, EPA published a product cancellation order for 47 product registrations covering a variety of pesticide chemical names. All registration cancellations were voluntarily requested by the registrants. In the *Federal Register* of March 12, 2015 (80 FR 12996), EPA published a notice of receipt of requests for cancellation and provided a 30-day public comment period. EPA received three comments which were all in agreement with the product cancellations. (Joseph Nevola, 703-308-8037).

EPA Meets with Monsanto to Discuss Glyphosate Registration Review. On June 4, the glyphosate team met with Monsanto, a technical registrant of glyphosate, to discuss the registration review of glyphosate. Topics discussed include the timing of registration review deliverables, weed resistance management, methods for detecting glyphosate in urine and breast milk, and measures for protecting pollinators. Glyphosate is a non-selective herbicide widely used to control weeds in agricultural crops and in non-agricultural areas. Agricultural crops include a variety of fruits, vegetables, and field crops. Non-agricultural use sites include forests, greenhouses, non-crop areas, and residential areas. Glyphosate is also registered for use on glyphosate-resistant crop varieties such as canola, corn, cotton, soybeans, sugar beets, and wheat. The registration review docket for glyphosate opened in 2009 and the Agency intends to issue preliminary human health and ecological risk assessments in fall 2015. (Khue Nguyen, 703-347-0248).

Meeting with Syngenta to Discuss Thiamethoxam Pollinator Studies. On June 2, members of OPP's thiamethoxam registration review team from EFED and PRD, along with partners from Health Canada's Pest Management Regulatory Agency and California Department of Pesticide Regulation met with representatives from Syngenta, Syngenta Canada, and Eurofin to discuss the thiamethoxam hive feeding study. Preliminary results of the study were presented. Updates on requested pollen and nectar residue studies were also provided. The Agency expects to receive the raw data from the hive feeding study in late summer – early fall, followed by submission of the final report by the end of the year. (Christina Motilall, 703-603-0522).

First Team Meeting Held for Strychnine Registration Review. On June 4, team members from BEAD, EFED, HED, PRD, and RD met to kick-off the registration review process for strychnine. Strychnine is a rodenticide registered for use belowground as a bait application to control pocket gophers. No additional data requirements are expected. It is anticipated that the opening of the strychnine registration review will include the Preliminary Work Plan, human health and ecological risk assessments, and proposed interim decision; significantly shortening the chemical's registration review timeframe. The registration review docket initiating a 60-day public comment period on strychnine is scheduled to open in December 2015. (Joel Wolf, 347-0228).

Boscalid Final Work Plan (FWP) Signed! The Boscalid FWP was signed on June 3. Boscalid is a fungicide registered for use on food crops, golf course turf, residential ornamentals, and landscape gardens. The FWP provides a summary of substantive comments received during the public comment period for the Preliminary Work Plan (PWP). The comments did not result in changes to the anticipated risk assessments or timeline. A Data Call-In for information needed to conduct the registration review risk assessments is expected to be issued this fall. See docket EPA-HQ-OPP-2014-0199 at www.regulations.gov. (Maria Piansay, 703-308-8063).

Spanish Pesticide Labeling Conference Call with States. On June 4, PRD and RD members of the OPP Spanish Labeling workgroup had a conference call with state lead agency representatives from Florida, Michigan, Virginia, and New Mexico to provide an update on the development of the Spanish Pesticide Labeling Pilot Program. The workgroup described the progress of the Translation Guide and requested feedback on the section of the Submission Guide that deals with submitting pilot labels to states. The states suggested that approval of pilot labels could be expedited and even offered to help with evaluation of pilot labels in the field. The workgroup will continue to work with these and other states directly and through the Association of American Pesticide Control Officials (AAPCO) as the pilot nears the launch date. (Jose Gayoso, 347-8652).

INFORMATION TECHNOLOGY & RESOURCES MANAGEMENT DIVISION

WebFPPS Link Added to OPP Intranet. The ITRMD Web Team added a new link, Federal Personnel and Payroll System (WebFPPS), to OPP@Work. This is a permanent link and is available in the Popular Links box, above eOPF with a 'new' icon. This will give managers easy access to the WebFPPS system. It is also listed in the Highlights box as a new addition to the Website and will be removed from the Highlights box as we update the page with more new items. (Feroz Daraseng, 703-347-0623)

<u>Web Analytics Completed on Web Pages</u>. The ITRMD Web Team provided web statistics using Google Analytics for the following pages:

- <u>EPA's Regulation of Biotechnology for Use in Pest Management</u> and <u>EPA's Regulation of Biotechnology for Use in Pest Management</u> From May 2014 thru April 2015
- Introduction to Biotechnology Regulation for Pesticides

Total Page Views: 2,310 Unique Page Views: 2,045

Average time on the page: 3 and ½ minutes

Data on the previous page and domain used to get to the page were also provided

• EPA's Regulation of Biotechnology for Use in Pest Management

Total Page Views: 1,118 Unique Page Views: 995

Average time on the page: 5 and ½ minutes

Data on the previous page and domain used to get to the page were also

provided

(Miriam Organic, 703-605-0583)

<u>Data Requirements Web Page Published</u>. The ITRMD Web Team worked with FEAD to prepare and publish the <u>Data Requirements</u> and the <u>Alternate Testing</u> <u>Framework for Classification of Eye Irritation Potential of EPA Pesticide Products</u> web pages. (Delphine Coleman, 703-305-5692)

<u>United States-Canada Regulatory Cooperation Council Initiatives on Pesticides</u>.

The ITRMD Web Team worked with FEAD to update the <u>Under the US-Canada</u>

<u>Regulatory Cooperation Council</u>, the <u>United States and Canada continue our</u>

<u>long-standing cooperation with the release of a Regulatory Partnership Statement</u>
(<u>RPS</u>) and <u>annual Work Plans</u>. New files have been added to the Additional
Information section of the web page. (Delphine Coleman, 703-305-5692)

OPP FOIA Request Status Report for May 25-29, 2015 **Requests Requests Closed Requests Open** Received This Prior This FY15 FY15 **FY15 FYTD** Total Week Week Years 6 214 12 134 242 376 340 335

(Sharon McBride, 703-305-5232)